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EDITORIAL

The quality of a registry based study depends on the quality of the data – without validation, it is questionable

In 1972, the AHA Committee of Vascular Surgery published a report that aimed to identify the resources required for performance of high quality vascular surgery. One of the recommendations in this report was that vascular surgeons keep standardised and detailed records so that their work may be readily judged by its results.[1] Indeed, it is crucial in vascular surgery to maintain a balance between the risks related to surgery and those related to the patient's disease. With borderline indications, such as asymptomatic carotid stenosis and abdominal aortic aneurysms (AAAs) close to 55 mm, the net benefit can easily be negative if the complication rates are above the standard. As already recommended almost 50 years ago, every vascular surgical unit should know their complication rates, as should every vascular surgeon. A vascular registry is the tool for controlling the quality of the performance and allowing continuous quality improvement.

The first multi-surgeon computerised vascular registry was established in Cleveland in 1975. In 1979, they reported the results of the first 8,824 procedures.[2] The mortality rate for all patients was 8.2% and for abdominal aortic reconstructions 10.8%. The authors concluded that it is possible to obtain a highly coordinated cooperative effort from vascular surgeons working in discrete geographic areas, and that the data gathered therein can be of value in a variety of ways. In the late 1980s and 1990s, population based national vascular registries were established in several parts of Europe: in Sweden (1987), in Denmark and Finland (1989), in Norway (1996), in the UK (1998), and, later on in several other countries.

As the experience with vascular registries increased, the validity of the registry data became an issue. In the first publication on the Swedvasc registry, a concern was expressed that, in some hospitals, only 20% of the cases were registered.[3] The Finnvasc registry was validated in 1994 and 1996. The external validity was 81–86%, ranging 53–100% between the hospitals.[4,5]

Poor external validity raises the question of the procedures that are not entered into the registry. Do they represent the average patient population, or is there a selection mechanism? There is some evidence that patients who are forgotten have worse outcomes compared with the registered ones.[6,7] The operations most likely not registered are those performed as emergencies, especially during the night.[5] In the latest validations of the Hungarian vascular registry and Swedvasc, the external validity of carotid endarterectomies and AAA reconstructions was extremely good, 94–109%.[8,9] On a population base level, external validation can be performed through comparison of the clinical registry with national administrative registries, and can be automated to ensure continuous annual evaluation of the external validity.

Even if the external validity is 100%, poor internal validity significantly weakens the quality of the registry. There are two aspects to internal validation: how correct are the recorded data, and what is the proportion of missing data. In the reports on internal validations, the procedural variables – such as the main indication, operation code, anatomy – have been well recorded. However, preoperative risk factors, especially smoking, have had a high proportion of missing data.[3–5,9] Immediate surgical complications and non-vascular re-operations have been highly valid.[6,9] Most crucial, however, is the validity of the follow-up data. The collection of follow-up data may be difficult, as not all patients are able to revisit the hospital. Non-vascular complications have more often been neglected than those associated with surgery.[6] Of the so called hard endpoints after vascular surgery, death and amputation are also registered in national mandatory registries. The possibility to link the vascular registry to the national database significantly increases the validity of the registry. This is currently the case at least in Swedvasc, the Danish vascular registry Karbase and Husvasc (vascular registry of the Helsinki University Hospital). This linkage allows for the examination of the long-term outcome. For example, after elective endovascular aneurysm repair (EVAR), the in hospital mortality is very low, but the risk of long-term RAAA mortality persists even 10 years after the primary EVAR, making long-term follow-up crucial.[10]

In the current issue of the Journal, two interesting studies related to registries are reported.[11,12] The first reports the results of AAA surgery during 1999–2010 in Germany, including 39,500 AAA repairs.[11] The mean age and proportion of patients with ASA 3–4 increased over the study period. The total in hospital mortality decreased from 3.1% to 2.3%, and the use of EVAR increased from 17% to 63% of the procedures. The authors concluded that the in hospital patient safety has improved, which is probably a result of the shift towards the less invasive method of treatment. Furthermore, the follow-up of the patients decreased from 17 to 10 days, as the data only include the in hospital outcome. The number of

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participating hospitals varied annually between 79 and 137 during the study period, and the paper does not include information on the number of hospitals that participated in the registry for the whole 12 year period. Unfortunately, neither external nor internal validation was carried out, and the proportion of missing data is not reported. Furthermore, no official data on deaths were available. Despite their limitations, the German data are valuable. It is a good example of the power of a registry and its ability to accrue a substantial database. It clearly shows the trends in demographics and the choice of the treatment method, as well as in outcome. Furthermore, the registry shows that half of the aneurysms were <55 mm, and 25% <50 mm in diameter. When treating these patients, the results should be extremely good, as the risk of rupture is low. The long-term outcome of these patients would also be important.

The second study investigated the accuracy of the peripheral artery disease (PAD) diagnosis in the Danish national patient registry.[12] It showed the vulnerability of diagnosis data in a national administrative registry because for one in three patients, the PAD diagnosis was not valid. The authors concluded that their study stressed the importance of the registry data validation. It emphasises not only the importance of validation, but also of measures taken to improve the validity. At the same time, the data validity of the Danish vascular registry was found to be good, and the authors concluded that the data could be used without further validation. This finding is to be expected, as a vascular registry is for procedures performed mostly because of PAD and used by vascular surgeons. However, the statement that the data of the registry could be used without further validation is only true when it comes to the diagnosis, but not automatically so when it comes to the other variables in the registry. The message of the Danish study is important and should encourage decision makers and researchers involved with registries, which are used for quality improvement decision making and research, to carry out systematic continuous validation.

Which measures can be taken to improve the validity of the data? Regular external and internal validation are of importance, and annual external validation should be routine. Continuous feedback to the operating surgeons on their performance would undoubtedly improve the motivation to enter cases into the registry, and thus validity. The VASCUNET collaboration, which held its first meeting during the European Society for Vascular Surgery (ESVS) meeting in Lisbon 20 years ago and has been an official working group of ESVS since 2004, joins together 12 registries from Europe, Australia, and New Zealand. The VASCUNET aims to improve the quality of vascular surgery and patient safety using national clinical registries. The VASCUNET group is well aware of the problems related to incomplete data as a source of bias and in the end, the risk of misleading messages. Therefore, a validation project was initiated in 2013, aiming for validation of all participating registries. So far, the validation has been completed for the Hungarian and Swedish registries. The group hopes to obtain resources to continue the validation project.

The editors of the Journal welcome the submission of high quality data from national registries, as they contribute to our scientific and clinical knowledge, and to continuous improvement in the vascular surgical care that we offer to our patients.

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